4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 117

[Docket No. FDA-2012-N-1258]

Draft Qualitative Risk Assessment of Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm; Availability; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA or "we") is reopening the comment period for a document entitled "Draft Qualitative Risk Assessment of Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm" (the draft RA) that we made available for public comment in the Federal Register of January 16, 2013. We are reopening the comment period to update comments and to receive any new information.

DATES: Submit either electronic or written comments by May 16, 2013.

ADDRESSES: Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of January 16, 2013 (78 FR 3824), we published a notification with a 30-day comment period announcing the availability of, and requesting comment on, a document entitled "Draft Qualitative Risk Assessment of Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm." The purpose of the draft RA is to provide a science-based risk analysis of those activity/food combinations that would be considered low risk. We conducted this draft RA to satisfy requirements of the FDA Food Safety Modernization Act (FSMA) to conduct a science-based risk analysis and to consider the results of that analysis in rulemaking that is required by FSMA. In the Federal Register of January 16, 2013 (78 FR 3646), we announced that we had used the results of the draft RA to propose to exempt certain food facilities (i.e., those that are small or very small businesses that are engaged only in specific types of onfarm manufacturing, processing, packing, or holding activities identified in the draft RA as low-risk activity/food combinations) from the proposed requirements of the Federal Food, Drug, and Cosmetic Act for hazard analysis and risk-based preventive controls (the proposed preventive controls rule). Interested persons were originally given until February 15, 2013, to comment on the draft RA.

II. Request for Comments

Following publication of the notification announcing the availability of, and requesting comment on, the draft RA, we received three requests to allow interested persons additional time to comment. The requesters asserted that the time period of 30 days was insufficient to respond fully to FDA's specific requests for comments and to allow potential respondents to thoroughly evaluate and address pertinent issues. Two requesters considered that the comment period for the draft RA should conform to the comment period of the proposed preventive controls rule. (One of these requesters further requested that the comment period conform to that of another proposed rule published in the Federal Register of January 16, 2013 (78 FR 3504; the proposed produce safety rule) and other major rulemakings that FDA would be conducting under FSMA but were not yet published.) For similar reasons, another requestor considered that the comment period should be extended by another 120 days, to June 14, 2013.

We have considered the requests and are reopening the comment period for the draft RA until May 16, 2013, which conforms to the comment periods of the proposed preventive controls rule and the proposed produce safety rule. We believe that this extension allows adequate time for interested persons to submit comments without significantly delaying the associated rulemaking in the proposed preventive controls rule.

III. How to Submit Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

Dated: March 7, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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